

**Link to Patents and Exclusivities Chart:**

List the currently approved patents or exclusivities for the reference listed drug in a table format such as the one shown below.

**Patent Data**

Appl No	Prod No	Patent No	Patent Expiration	Patent Use Code	Patent Certification	Labeling Impact

**Patent Use Code    Definition****Exclusivity Data**

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration	Labeling Impact

**Exclusivity Code    Definition**

Patent Use or Exclusivity Code definitions should be as defined in the Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

Statements appropriate for the Patent Data Labeling Impact column are as follows:

- No labeling changes (i.e., your patent certification has no impact on the content of labeling and the insert will be the same as the reference listed drug)
- Carve Out (i.e., based on your method of use certification you intend to remove or carve out the protected indication(s) from the insert.)

Statements appropriate for the Exclusivity Data Labeling Impact column are as follows:

- wait until exclusivity expires to market drug (i.e., the insert will be the same as the reference listed drug)
- carve out protected indication (i.e., you intend to remove or carve out the protected indication(s) from the insert.)